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10/658,736	09/09/2003	Alan Shluzas	ENDIUS.26CPCP2	3377

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EXAMINER	
WOODALL, NICHOLAS W	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/658,736	Applicant(s) SHLUZAS ET AL.	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/02/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 03/02/2007.

Allowable Subject Matter

2. The indicated allowability of claims 21 and 26 is withdrawn in view of the newly discovered reference(s) to Boyd, Aust, and Luque. Rejections based on the newly cited reference(s) follow.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/630,077, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application 09/630,077 fails to provide support for a multi-level procedure through the access device. Therefore, claims 1-32 are not entitled to the benefit of the prior application.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 6-9, 11-13, 18, 19, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (U.S. Patent 5,683,391) in view of Davison (U.S. Publication 2001/0011170).

Regarding claim 1, Boyd discloses a method of treating a spine comprising the steps of implanting a fusion device via an anterior approach in an interbody space between at least two of a first vertebra, a second vertebra, and a third vertebra and performing a multi-level procedure across the at least three vertebrae. Regarding claim 6, Boyd discloses the method wherein the multi-level procedure is fixation. Regarding claim 7, Boyd discloses a method wherein the fixation is performed via an anterior approach. Regarding claim 8, discloses a method further comprising performing a fusion procedure external to the interbody space after performing fixation. Regarding claim 9, Boyd discloses a method further comprising decompression prior to performing fixation. The examiner is interpreting decompression to include any procedure that reduces pressure on the spinal cord. Therefore procedures such as removing intervertebral disc material to prepare the interbody space and other procedures such as laminotomy, laminectomy, and facetectomy. Boyd discloses a method wherein a discectomy is performed to prepare the intervertebral space prior to inserting the

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performing fixation and further discloses performing further decompression after fixation (column 5 lines 22-28 and column 6 lines 52-63). Regarding claim 11, Boyd discloses a method wherein the multi-level procedure further comprises delivering a bone growth substance. Regarding claims 12 and 13, Boyd discloses a method further comprising performing decompression before and after delivering the bone growth substance. As discussed above procedures such as discectomy, laminotomy, laminectomy, and facetectomy are being considered as decompression procedures since all relieve pressure on the spinal cord. Regarding claim 18, Boyd discloses a method comprising the steps of anteriorly exposing an interbody space between at least two of a first vertebra, a second vertebra, and a third vertebra, placing a fusion device in the interbody space, and placing bone growth substance adjacent an interbody space defined by at least two of the first vertebra, second vertebra, and third vertebra. Regarding claim 19, Boyd discloses a method further comprising the steps of using a decompression tool to remove a portion of bone from the first vertebra, second vertebra, and third vertebra. Regarding claim 30, Boyd discloses a method wherein the fusion device is a fusion cage. Regarding claim 32, Boyd discloses a method comprising the steps of implanting a fusion device via an anterior approach in an interbody space between at least two of a first vertebra, a second vertebra, and a third vertebra and performing a multi-level procedure across the at least three adjacent vertebrae. Boyd fails to disclose the methods as discussed above further comprising performing the above methods through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a

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second dimension in the second configuration. Davison teaches performing spinal surgeries through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in order to perform the methods through relatively small incisions and reduce the trauma experienced by the patient (page 1 paragraph 002). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the methods of Boyd to further include performing the methods through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in view of Davison in order to perform the methods through relatively small incisions and reduce the trauma experienced by the patient.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (U.S. Patent 5,683,391) in view of Davison (U.S. Publication 2001/0011170) further in view of Luque (U.S. Patent 4,790,297).

Regarding claim 10, the combination of Boyd and Davison disclose the invention as claimed except the method further comprising the step of performing a fusion procedure external to the interbody space after performing fixation. Luque teaches a method further comprising the step of performing a fusion procedure external to the interbody space after performing fixation, i.e. introducing bone chips over the decorticated transverse process, in order to facilitate fusion between the fixation elements and the vertebrae. It would have been obvious to one having ordinary skill in

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the art at the time the invention was made to perform the method of Boyd modified by Davison to include the step of performing a fusion procedure external to the interbody space after performing fixation in view of Luque in order to in order to facilitate fusion between the fixation elements and the vertebrae.

7. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (U.S. Patent 5,683,391) in view of Davison (U.S. Publication 2001/0011170) further in view of Foley (U.S. Patent 5,792,044).

Regarding claims 3-5, the combination of Boyd and Davison disclose the invention as claimed except for the access device being inserted via multiple approaches, i.e. postero-lateral, transaminial, and posterior. Foley teaches an access device capable of being inserted via multiple approaches in order to allow multiple spinal procedures to be performed with the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the methods of Boyd modified by Davison to further include the device being inserted via multiple approaches in view of Foley in order to allow multiple spinal procedure to be performed with the device.

8. Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aust (U.S. Patent 5,603,713) in view of Davison (U.S. Publication 2001/0011170).

Regarding claims 14 and 17, Aust discloses a method of treating a spine comprising anteriorly exposing an interbody space between at least two of a first vertebra, a second vertebra, and a third vertebra, placing a fusion device made from a bone growth substance in the interbody space, providing a first fastener for attachment

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to the first vertebra, providing a second fastener for attachment to the second vertebra, providing a third fastener for attachment to a third vertebra, attaching the fasteners to the vertebrae, providing an elongate member and moving the elongate member adjacent the fasteners, and securing the elongate member to the fastener. Aust fails to disclose the methods as discussed above further comprising performing the above methods through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration. Davison teaches performing spinal surgeries through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in order to perform the methods through relatively small incisions and reduce the trauma experienced by the patient (page 1 paragraph 002). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the methods of Aust to further include performing the methods through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in view of Davison in order to perform the methods through relatively small incisions and reduce the trauma experienced by the patient.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aust (U.S. Patent 5,603,713) in view of Davison (U.S. Publication 2001/0011170) further in view of Boyd (U.S. Patent 5,683,391).

Regarding claims 15 and 16, Aust discloses a method of treating a spine comprising anteriorly exposing an interbody space between at least two of a first vertebra, a second vertebra, and a third vertebra, placing a fusion device manufactured from a bone growth substance in the interbody space, providing a first fastener for attachment to the first vertebra, providing a second fastener for attachment to the second vertebra, providing a third fastener for attachment to a third vertebra, attaching the fasteners to the vertebrae, providing an elongate member and moving the elongate member adjacent the fasteners, and securing the elongate member to the fastener as discussed above for claim 14. The combination of Aust and Davison fail to disclose the method further comprising using a decompression tool to remove a portion of bone from the first, second, and third vertebrae. Boyd teaches a method of treating a spine further comprising the step of using a decompression tool to remove a portion of bone from the first, second, and third vertebrae in order to further correct any deformity in the frontal plane (column 6 lines 52-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Aust modified by Davison further comprising the step of using a decompression tool to remove a portion of bone from the first, second, and third vertebrae in view of Boyd in order to further correct any deformity in the frontal plane.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aust (U.S. Patent 5,603,713) in view of Davison (U.S. Publication 2001/0011170) further in view of Michelson (U.S. Patent 6,123,705).

Regarding claim 31, the combination of Aust and Davison disclose the invention as claimed except for the fusion device being a spinal cage. Michelson discloses a method for treating the spine comprising a fusion device that is a spinal cage filled with bone growth material in order to enhance stability during fusion (column3 lines 13-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Aust modified by Davison wherein the fusion device is a spinal cage filled with a bone growth material in view of Michelson in order to enhance stability during fusion.

11. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews (U.S. Patent 6,033,406) in view of Foley (U.S. Patent 5,792,044).

Regarding claims 20, 24, 28, and 29, Mathews discloses a method of treating the spine via a posterior approach comprising placing a fusion device, i.e. a bone graft, in at least one of a first interbody space between the first and second vertebrae and a second interbody space between the second and third vertebrae, and performing a two level fixation procedure. Mathews fails to disclose the method further comprising using a decompression tool to perform a decompression procedure on one of the first, second, and third vertebrae. Foley teaches a method of treating a spine further comprising the step of using a decompression tool to perform a decompression procedure, i.e. laminectomy and facetectomy, on one of the first, second, and third vertebrae in order to reduce pressure on the spinal cord. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Mathews further including the step of using a decompression tool to perform a

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decompression procedure, i.e. laminectomy and facetectomy, on one of the first, second, and third vertebrae in view of Foley in order to reduce pressure on the spinal cord.

12. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews (U.S. Patent 6,033,406) in view of Foley (U.S. Patent 5,792,044) further in view of Davison (U.S. Publication 2001/0011170).

Regarding claims 20-29, the combination of Mathews and Foley disclose the invention as claimed except for the method as discussed above further comprising performing the above method through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration. Davison teaches performing spinal surgeries through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in order to perform the methods through relatively small incisions and reduce the trauma experienced by the patient (page 1 paragraph 002). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Mathews modified by Foley to further include performing the method through an access device having a first and second configuration, wherein the distal portion expands from a first dimension in the first configuration to a second dimension in the second configuration in view of Davison in order to perform the method through relatively small incisions and reduce the trauma experienced by the patient.

Response to Arguments

13. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection for claims 1-32. Since previously indicated allowability of claims 21 and 26 is withdrawn this office action is non-final.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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